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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,691	04/18/2002	Victor Uebele	20499P	8269

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MERCK AND CO., INC
P O BOX 2000
RAHWAY, NJ 07065-0907

EXAMINER

MERTZ, PREMA MARIA

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 04/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/031,691	Applicant(s) UEBELE ET AL.	
	Examiner Prema M. Mertz	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 February 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,6-8,12,13 and 15-45 is/are pending in the application.
- 4a) Of the above claim(s) 13 and 15-42 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 8 is/are allowed.
- 6) ☒ Claim(s) 1,3,4,6-7 and 12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Claims 13, 15-42 have been withdrawn from consideration. Claims 2, 5, 9-11, 14 have been canceled (2/22/2005). Amended claims 1, 3-4, 6-8, 12 (2/22/2005) and new claims 43-45 are under consideration.
2. Receipt of applicant's arguments and amendments filed on 2/22/2005 is acknowledged.
3. The following previous rejections and objections are withdrawn in light of applicants amendments filed on 2/22/2005:
 - (i) the rejection of claim 12 under 35 U.S.C. 101;
 - (ii) the rejection of claims 1, 6-7 under 35 U.S.C. 112, first paragraph for scope of enablement;
 - (iii) the rejection of claims 1, 4, 5-8, 10-12, 14 under 35 U.S.C. 102(b) as being anticipated by WO 00/12711.
4. Applicant's arguments filed on 2/22/2005 have been fully considered and were persuasive in part. The remaining issues as well as new issues are stated below.
5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim rejections-35 USC § 112, first paragraph

6. Claims 43-45 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 43 recites “heterologous” in line 1 and line 3 and claim 44 recites “heterologous” in line 1 and line 3, which language is new matter in the claim, since the instant specification fails to disclose such a limitation. The specification fails to provide proper support for this language in the claims for the following reason:

In the specification page 20, lines 8-11 discloses:

The $\beta 2$, $\beta 3a$, $\beta 3b$, $\beta 3c$, or $\beta 3d$ subunits of the human calcium sensitive potassium channel have been expressed in *Xenopus* oocytes, both by themselves and in combination with an α subunit of a large-conductance calcium-sensitive potassium channel (maxi-K channel).

In the specification page 50, lines 20-24 discloses:

Electrophysiological analysis: cRNAs were synthesized in vitro from plasmids encoding human Slowpoke α or the $\beta 2$, $\beta 3a$, $\beta 3b$, $\beta 3c$, or $\beta 3d$ subunits and injected into *Xenopus* oocytes (1.5 ng/oocyte of α subunit RNA +/- β subunit RNA at 1, 5, or 10X molar excess).

The specification does not disclose the specific limitations of “heterologous” as recited in the claims 43-44. This rejection can only be obviated by reciting the language for which there is support in the instant specification.

Furthermore, claim 45, line 5 recites “transferring the expression vector”, and line 6 recites “amplification of the vector” which language is new matter in the claim, since the instant specification fails to disclose such limitations. This rejection can only be obviated by reciting the language for which there is support in the instant specification.

7. Claim 12 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated polypeptide comprising the amino acid sequence set forth in SEQ ID N0:2, does not reasonably provide enablement for a

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polypeptide comprising an amino acid sequence with at least 80% amino acid sequence identity to the protein of SEQ ID NO:2.

This rejection is maintained for reasons of record set forth at pages 18-19 of the previous Office action (10/22/2004).

Applicants argue on page 1 of the arguments that claim 12 has been canceled rendering moot the outstanding 35 U.S.C. 112, first paragraph rejection for the recitation of "80% sequence identity" in the claim. However, contrary to Applicants argument, this claim is pending and the rejection is being maintained for reasons of record.

Claim rejections-35 USC § 112, second paragraph

8. Claims 1, 3-4, 6-7, 12, are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is confusing for reciting "designated β 2". It is suggested that for clarity the claim be amended to delete the recitation of the name of the subunit in the claim but to recite an isolated nucleic acid encoding a protein comprising the amino acid sequence of SEQ ID NO:2 and the function of the encoded protein.

Claim 12 is vague and indefinite because it recites "polypeptide having at least 80% sequence identity to the protein". It is suggested that for the sake of consistency, the terms "polypeptide" and "protein" not be used interchangeably.

Claims 3-4, 6-7, are rejected as vague and indefinite insofar as they depend on claim 1 for its limitations.

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Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

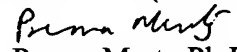
Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (571) 272-0829.

Official papers filed by fax should be directed to (571) 273-8300. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Information regarding the status of an application may be obtained from the Patent application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Prema Mertz Ph.D.
Primary Examiner

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March 25, 2005